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10/06/05

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NOTICE OF ACCEPTANCE

Re: Patent Application No. 57799 / 00 in the name of:
J. Alexander Marchosky

Your Reference:

The examiner has reported no objections to the application and complete specification as amended by the following alterations:

Item number(s) Specification 1-3
Application
Drawings

The application and complete specification were accepted on 10/06/05 and a notice of the acceptance will appear in the Official Journal of Patents on 21/07/05 under serial number 782394

All future correspondence should refer to this serial number.

Your patent will be sealed as soon as practicable after the 3 month period for opposition has expired.

You are reminded that, except where your application has undergone modified examination, you are required under subsection 45(3) to inform the Commissioner of the results of any searches carried out prior to the grant of the patent.

Enclosed for your information, are details of the application data at acceptance. This data will be the basis for any Deed that may later be issued. At present there is no provision under the Patents Act to reissue Deeds. It is, therefore, important that you notify this office of any changes before the opposition period expires.

Maria LEWIS
Patent Notification
Ext. 2020

PATADMIN DETAILS FOR PATENT APPLICATION NO. 57799 / 00
Serial Number : 782394

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Acceptance Date: 10/06/05 Acceptance to be Advertised: 21/07/05

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Applicant Name : J. Alexander Marchosky
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Title: Compositions and methods for forming and strengthening bone

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Prior Art Documents:
EP 0522569

PRIORITY DETAILS

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The claims defining the invention are as follows:

1. A composition comprising:

(a) one or more materials selected from the group consisting of fibroblast growth factors, vascular endothelial growth factors, endothelial cell growth factors, transforming growth factors, chitosan, bone, platelet derived endothelial growth factors, placental growth factors, angiogenin, interleukin-8, granulocyte colony- stimulating growth factor, and supernatant fluid from a culture of cells known to produce angiogenic factors, wherein the one or more materials are present at 10^{-6} to 30 mg/ml;

(b) a material comprising demineralized bone matrix with or without hyaluronic acid;

(c) a scaffolding material selected from the group consisting of cancellous bone, chitosan, chitosan-protein, and chitin-protein fibers; and

(d) a gel material selected from the group consisting of chitosan, imidazolyl chitosan, methylpyrrolidinone chitosan, carbodiimide chitosan, glutaraldehyde chitosan, a mixture comprising alginate and chitosan , alginate, hyaluronic acid, and a mixture comprising hyaluronic acid and chitosan.

2. The composition of claim 1, wherein the one or more materials is an effective amount of a fibroblast growth factor or a vascular endothelial growth factor; the demineralized bone matrix is present at 10%; the cancellous bone is present at 10%; and the gel material is selected from the group consisting of a 3% (w/v) concentration of alginate and a mixture of alginate and chitosan.

3. The composition of claim 1, wherein the one or more materials comprise an effective amount of a fibroblast growth factor or a vascular endothelial growth factor; the demineralized bone matrix is present at 20%; the cancellous bone is present at 20%; and the gel material is selected from the group consisting of a 3% (w/v) concentration of alginate and a mixture of alginate and chitosan.

4. The composition of claim 1, wherein the one or more materials is an effective amount of fibroblast growth factors or vascular endothelial growth factors; the demineralized bone matrix is present at 10%; the cancellous bone is present at 30%; and the gel material is a 3% (w/v) concentration of alginate, or a mixture of alginate with chitosan.

5. The composition of claim 1, wherein the one or more materials is an effective amount of fibroblast growth factors or vascular endothelial growth factors; the demineralized bone matrix is present at 10-15% (w/w); the cancellous bone is present at 15-25% (w/w); and the gel material is a 3% (w/v) concentration of alginate, or a mixture of alginate with chitosan.

6. A composition when used for promoting the growth and strengthening of bone comprising a mixture of a chitosan , cancellous bone, and demineralized bone matrix.

7. A composition of claim 6, wherein said demineralized bone matrix is present at 10%; the cancellous bone is present at 10%; and wherein the chitosan is present at 3% (w/v) and comprises a gel material.

8. A composition of claim 6, wherein the demineralized bone matrix is present at 20%; the cancellous bone is present at 20%; and wherein the chitosan is present at 3% (w/v) and comprises a gel material.

9. A composition of claim 6, wherein the demineralized bone matrix is present at 10%; the cancellous bone is present at 30%; and wherein the chitosan is present at 3% (w/v) and comprises a gel material.

10. A composition when used for promoting the growth and strengthening of bone comprising a mixture of alginate, calcium, cancellous bone, and demineralized bone matrix.

11. A composition of claim 10, wherein said demineralized bone matrix is present at 10%; the cancellous bone is present at 30%; and the alginate is present at 3% (w/v) with or without calcium, and comprises a gel material.

12. A composition of claim 10, wherein said demineralized bone matrix is present at 20%; the cancellous bone is present at 20%; and the alginate is present at 3% (w/v) with or without calcium, and comprises a gel material.

13. A composition of claim 10, wherein said demineralized bone matrix is present at 10%; the cancellous bone is present at 10%; and the alginate is present at 3% (w/v) with or without calcium, and comprises a gel material.

14. A composition when used for promoting the growth and strengthening of bone comprising a mixture of chitosan , alginate, cancellous bone, and demineralized bone matrix.

15. A composition of claim 14, wherein said demineralized bone matrix is present at 20% (w/w); the cancellous bone is present at 12% (w/w); the alginate is present at 0.5% (w/w) and the chitosan is present at 0.3% (w/w) .

16. A composition when used for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix, and, optionally, one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone.

17. A composition as set forth in claim 16, wherein the cancellous bone is present at 10-50% (w/w).

18. A composition as set forth in claim 17, wherein the cancellous bone is 0.1-1.5 mm in its longest diameter.

19. A composition as set forth in claim 16, wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

20. A composition as set forth in any one of claims 16 to 19, further comprising one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone.

21. A composition as set forth in claim 20, further comprising vascular endothelial growth factor.

22. A composition as set forth in claim 21, wherein the vascular endothelial growth factor is present at 10^{-6} to 30 mg/ml.

23. A composition as set forth in any one of claims 16 to 22, wherein the cancellous bone is present at 5-30%.

24. A method of inducing bone formation in a vertebrate comprising applying a composition selected from the group consisting of a composition of any one of claims 1-23 to a site in the vertebrate where bone formation is desired.

25. The method of claim 24, wherein the site is the junction of an allograft or autograft and a bone.

26. The method of claim 24, wherein the site is the junction of a bone and a bone prosthesis.

27. The method of claim 24, wherein the site is a fracture.

28. A method of inducing bone formation in a vertebrate comprising applying an effective amount of a composition consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix, and, optionally, one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone, wherein any bone material consists essentially of bone allograft material, to a site in the vertebrate where bone formation is desired.

29. A method of inducing bone formation in a vertebrate as set forth in claim 28, wherein the cancellous bone is present at 10-50% (w/w).

30. A method of inducing bone formation in a vertebrate as set forth in claim 28, wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

31. A method of inducing bone formation in a vertebrate as set forth in claim 28, wherein the cancellous bone is present at 10-50% (w/w).

32. A method of inducing bone formation in a vertebrate as set forth in claim 28, wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

33. A method of filling a bone defect comprising filling the bone defect with a composition consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix, and, optionally, one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone.

34. A method of filling a bone defect as set forth in claim 33, wherein the bone defect comprises a spinal disc.

35. A method of filling a bone defect as set forth in claim 33, wherein any bone material consists essentially of bone allograft material.

36. The method of claim 35, wherein the site is the junction of an allograft or autograft and a bone.

37. The method of claim 35, wherein the site is the junction of a bone and a bone prosthesis.

38. The method of claim 35, wherein the site is a fracture.

39. A composition consisting essentially of a mixture of hyaluronic acid, cancellous bone and demineralized bone matrix, and, optionally, one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone, wherein any bone material consists essentially of bone allograft material.

40. A composition as set forth in claim 39, wherein the cancellous bone is present at 10-50% (w/w).

41. A composition as set forth in claim 39, wherein the cancellous bone is milled to 0.1-1.5 mm in its longest diameter.

42. A composition as set forth in claim 39, wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

43. A composition as set forth in in any one of claims 39 to 42, further comprising one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors,

granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone.

44. A composition as set forth in claim 43, further comprising vascular endothelial growth factor.

45. A composition as set forth in claim 44, wherein the vascular endothelial growth factor is present at 10^{-6} to 30 mg/ml.

46. A composition as set forth in any one of claims 39 to 45, further comprising a non-decalcified bone matrix present at 5-30%.

47. A composition when used for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix, and, optionally, one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth factors, tumor necrosis factor, endothelial cell growth factors, platelet derived growth factors, transforming growth factors, placental growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics, vitamins and non-decalcified bone.

48. A composition as set forth in claim 47, wherein the cancellous bone is present at 10-50% (w/w).

49. A composition as set forth in claim 47, wherein the cancellous bone is 0.1-1.5 mm in its longest diameter.

50. A composition as set forth in claim 47, wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix is present at 5-30%.

51. A method of inducing bone formation in a vertebrate comprising applying a composition as set forth in claim 91 to a site in the vertebrate where bone formation is desired.

52. A method as set forth in claim 51, wherein the cancellous bone is present at 10-50% (w/w).

53. A method as set forth in claim 52, wherein the cancellous bone is 0.1-1.5 mm in its longest diameter.

54. A method as set forth in claim 51, wherein the hyaluronic acid is present at 10-80% (w/w), the cancellous bone is present at 10-40% (w/w), and the demineralized bone matrix present at 5-30%.

55. A method of inducing bone formation in a vertebrate comprising applying a composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid, cancellous bone, demineralized bone matrix, and one or more compounds selected from the group consisting of vascular endothelial growth factor, bone morphogenetic proteins, fibroblast growth facts, tumor necrosis factor, endothelial cell growth factors, granulocyte colony-stimulating growth factors, insulin growth factors, interleukins, cytokines, antibiotics and vitamins.

56. The method of claim 55, wherein any bone material consists essentially of bone allograft material.

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